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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,315	01/18/2002	Katharine M. Martin	J&J-2086	1178

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AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER

1617

DATE MAILED: 01/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant No.	Applicant(s)
	10/052,315	MARTIN ET AL.
Examiner	Art Unit	
Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 October 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 18 and 20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 17, 19, and 21-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's preliminary amendment in response to the Restriction Requirement in Paper No. 6, submitted October 18, 2002 is acknowledged. Claims 21-28 are newly submitted. Currently, claims 1-28 are pending in this application.

Election/Restrictions

Applicant's election with traverse of the invention of Group II, claims 17 and 19, in Paper No. 6 submitted October 18, 2002 is acknowledged.

The traversal is on the ground(s) that no serious burden is placed upon the Office to search and examine the claims of Group I, II, and III together. This is not found persuasive because the invention of Group I is drawn to a composition comprising the ingredient specified herein whereas Group II is drawn to a method of regulating the firmness, tone, or texture of skin of a subject, employing the composition of Group I. The invention of Group III is drawn to another different method of treating environmental damage of skin of a subject. The inventions of Group I and II are separate and distinct, related as product and process of use, as discussed in the Requirement for Restriction mailed August 13, 2002. See the Restriction Requirement page 2. Therefore, the inventions of Groups I and II are seen to be separate and distinct inventions properly restricted from each other. Further, as discussed in the Restriction Requirement, the inventions of Groups II and III are seen to be separate and distinct inventions properly restricted from each other.

Thus, the search for the inventions of both Groups I, II, and III together would place an undue burden on the Office. Note regarding the classification of the inventions

herein that the search is not limited to the patent files. The search field for a composition is non-coextensive with the search field for a method of regulating the firmness, tone, or texture of skin of a subject or a method of treating environmental damage of skin of a subject employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103. The composition and method herein have separate consideration as to patentability.

The requirement is still deemed proper and is therefore made FINAL. Claims 17, 19, and 21-28 will be examined on the merits herein.

Claims 1-16, 18, and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 19, and 21-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to the methods of regulating the firmness, tone, or texture of skin of a subject or regulating wrinkles in skin of a subject. The instant

specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

In the instant case:

Nature of the invention: The instant invention pertains to the methods of regulating the firmness, tone, or texture of skin of a subject or regulating wrinkles in skin of a subject, i.e., preventing, retarding, arresting, or reversing the wrinkles in the skin (see page 3 of the instant specification).

The state of the prior art: The skilled artisan would view that the treatment to regulate the firmness, tone, or texture of skin of a subject or regulate wrinkles in skin of a subject, i.e., preventing, retarding, arresting, or reversing the wrinkles in the skin, is highly unlikely. Over the years many attempts at stopping the aging process have been

recorded. However, they have later been proven unsuccessful. There is no fountain of youth. The results of many methods of pharmacological treatments have been uniformly unreliable and unsatisfactory.

The predictability or lack thereof in the art: The skilled artisan would view that regulation of the firmness, tone, or texture of skin of a subject or regulation of wrinkles in skin of a subject, i.e., preventing, retarding, arresting, or reversing the wrinkles in the skin, is highly unpredictable.

The presence or absence of working examples: In the instant case, no working examples are presented in the specification as filed showing how to use the herein to regulate the firmness, tone, or texture of skin of a subject herein. Applicant's specification provides the experimental results merely showing in vitro effects of a hedychium extract (see page 11-15 of the specification).

Therefore, in view of the Wands factors, as discussed above, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 19, and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "safe" in claim 17 is a relative term which renders claims 17, 19, and 21-28 indefinite. The term "safe" is not defined in the specification and claim. Therefore, the scope of claims is indefinite as to the composition encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 19, and 21-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiseido Co. Ltd (JP 61291515, PTO-1449 submitted November 6, 2002).

Shiseido Co. Ltd discloses that a hedychium extract in an effective amount, within the instant claim, is useful in a cosmetic composition with a cosmetically-acceptable carrier for topical administration and a method of treating hot feeling after sunburn, rough skin, razor rash and inflammations. See in JP 61291515, the abstract, and examples at page 65-69. Shiseido's method inherently treats the skin in a subject for regulating the firmness, tone, or texture of skin of a subject or for regulating wrinkles in skin of a subject, as claimed herein since Shiseido's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195

USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, Shiseido Co. Ltd anticipates the claimed invention.

Claims 17, 19, and 21-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lion Corp (JP 59181202, PTO-1449 submitted November 6, 2002).

Lion Corp discloses that a hedychium extract in an effective amount, within the instant claim, is useful in a topical composition with a cosmetically-acceptable carrier for human skin application for the treatment for insect repelling. See in JP 59181202, the abstract, and examples at page 3. Lion Corp's method inherently treats the skin in a subject for regulating the firmness, tone, or texture of skin of a subject or for regulating wrinkles in skin of a subject, as claimed herein since Lion Corp's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency as it related to the claimed invention herein. Thus, Lion Corp anticipates the claimed invention.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
December 30, 2002


THEODORE J. CRIARES
PRIMARY EXAMINER
GROUP 1200/600